Remarks

Applicants respectfully request reconsideration of this application in view of the following remarks.

Status of the Claims

Claims 1-40 are pending in this application of which Claim 12-19 and 27-40 are withdrawn from consideration. No amendments to the claims have been made in this response and therefore, Claims 1-40 remain pending in this application.

Restriction Requirement

In the pending Office Action, Applicants' election with traverse of Group I, Claims 1-11 and 20-26, was acknowledged and the restriction requirement was made final. According to 37 C.F.R. §1.144, Applicants have thus preserved their right to petition the Commissioner to review the restriction requirement.

Information Disclosure Statements

Applicants have noted the following discrepancies in the record of the information disclosure statements (IDS) submitted in this application: (1) The IDS submitted 7/25/03 was listed in the Office Action, but an initialed copy was not provided, and (2) The IDS submitted 1/7/04 was not listed, but an initialed copy was provided.

In addition, Applicants submit herewith an IDS and accompanying Form PTO/SB/08a listing WO 01/42193, the international publication corresponding to US 6,576,793 B1, of record. The reference was cited in the International Search Report for the corresponding PCT Application No. PCT/US03/23214. A copy of the International Search Report was provided with the IDS submitted 1/7/04.

Applicants respectfully request the Examiner return an initialed copy of the forms PTO/SB/08a submitted herewith and submitted previously on 7/25/03. Applicants would be pleased to provide a duplicate copy of the latter document for the Examiner's convenience if it is not readily available.

Rejection of Claims 1-11 and 20-26 under 35 U.S.C. §103(a)

Claims 1-11 and 20-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Moran et al. (US 6,576,793 B1). Applicants respectfully traverse the rejection.

The present rejection is based on the patentability of an optically active isomer over a prior art racemate. (Office Action page 4, lines 6-9 and 10-15) Applicants respectfully submit the Examiner has overlooked an essential feature of the present invention, namely that a specific crystalline salt of a chemical compound is what is being claimed.

The specification discloses that β_2 adrenergic receptor agonists are recognized as effective drugs for the treatment of pulmonary diseases and that *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine (compound **1**) has been identified as a potent β_2 adrenergic receptor agonist. (page 1, lines 17-26) Further, it discloses "active agents for the treatment of pulmonary diseases are advantageously administered by inhalation. ... Preparation of formulations for administration by inhalation typically relies on the existence of a crystalline form of the active agent, or of a crystalline form of a pharmaceutically acceptable salt of the active agent, having suitable physical and chemical properties." (page 2, lines 1-8) "No **crystalline** form of compound **1** or of a salt thereof, nor of a formulation comprising compound **1** that is suitable for administration by inhalation has been reported previously." (page 2, lines 17-19) (emphasis added)

The present claims are directed to a crystalline form of one particular pharmaceutically acceptable salt of compound **1**. Claim 1 specifically recites:

> 1. **Crystalline** *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine **dihydrochloride** (emphasis added)

The cited reference does not teach a dihydrochloride salt of compound **1** nor does it teach any crystalline compounds at all. Hence, the reference does not teach nor imply the specific crystalline dihydrochloride salt of compound **1** of the present invention. Accordingly, the present rejections of Claim 1 and, for similar reasons, of Claims 2-11 and 20-26 may be withdrawn.

Conclusion

In view of the foregoing, Applicants respectfully submit Claims 1-11 and 20-26 are in condition for allowance. Further, upon allowance, according to *In re Ochiai* (71F. 3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and MPEP §821.04, the restriction between Group I and Groups III and V (process claims) and between Group I and Group VI (method of use claims) may be withdrawn. Reconsideration of this application is respectfully requested. Should there be any issues regarding this application that may be resolved by telephone, the examiner is invited to telephone the undersigned agent for Applicants at (650) 808-3764 (direct).

Respectfully submitted,

THERAVANCE, INC.

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By: Roberta P. Saxon
Roberta P. Saxon, Ph.D.
Registration No. 43,087

THERAVANCE, INC.
901 Gateway Boulevard
South San Francisco, CA 94080
Tel: (650) 808-6000
Fax: (650) 808-6078